REMARKS/ARGUMENTS

In response to the Office Action of September 19, 2005, Applicant requests re-examination and reconsideration of this application for patent pursuant to 35 U.S.C. 132.

Claim Status/Support for Amendments

Claims 36, 37, 40 and 41 have been amended. Claim 1 has been cancelled. Claims 2-35 were cancelled in a previous response (filed on June 13, 2003). Claims 36-43 are currently under examination and remain pending in the instant application.

No new matter has been added by the amendments to the claims made herein.

Claim 36 has been amended to clearly delineate the steps of the claimed method(for diagnosing insulin resistance) and to clarify that the diagnosing of insulin resistance is accomplished by determining the presence of the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1. The biopolymer marker was found in patients having a history of insulin resistance (see the table in Figure 1).

Step (a) of claim 36 has been amended to clarify how the mass spectrometric analysis is carried out. Prior art mass spectrometric techniques often failed to identify the entire range of proteins

present in a sample; for example, the proteins present in the greatest amounts were most easily identified by these techniques. The claimed method overcomes this limitation of the prior art by the use of preparatory steps, such as chromatography and electrophoresis, prior to analysis of a sample using mass spectrometric techniques. These preparatory steps help to maximize the diversity of biopolymers discernible in a sample; i.e. the preparatory steps of the instant invention allow the identification of more biopolymers(including the less abundant proteins) present in a sample than previous methods allow. Thus, it is important for the claim to recite that a sample can be more throughly analyzed (maximized analysis) using the claimed method over prior art methods. See the abstract; page 11, lines 1-14; page 12, lines 2-6; page 17, lines 15-18 and page 20, line 7 to page 25, line 9 of the instant specification as originally filed.

Steps (a) and (b) of claim 36 have been amended to clarify how the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1 is identified in a sample. It is well known to the skilled artisan that mass spectral profiles are reproducible. Thus, the mass spectral profile of the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1, as shown in Figure 2, can be used as a reference against which to compare unknowns. For example, if the characteristic mass spectral profile of the biopolymer

marker consisting of amino acid residues 2-25 of SEQ ID NO:1 is matched to a mass spectral profile obtained in an analysis of an unknown sample, then the biopolymer marker is determined to be present in the sample and is therefore indicative of insulin resistance in the patient from which the sample was obtained (Figure 2 and page 27, lines 17-23 of the instant specification as originally filed) .

Claim 37 has been amended to provide proper antecedent basis to the term "sample" in parent claim 36.

Claim 40 has been amended to clarify that the claimed method may be carried out using a sample from a human. For support, see Figure 1 which shows a data table listing patient histories.

Claim 41 has been amended to clarify that the antibody of step (b) binds to the peptide of step (a). The specification as originally filed clearly contemplates kits useful for diagnosing insulin resistance that comprise the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1 and an antibody which binds to this biopolymer marker; see for example, page 17, line 19 to page 18, line 7; pages 27, lines 17-23; page 28, lines 1-8 and page 31, line 8 to page 33, line 2.

Rejections under 35 USC 102

Claim 1, as presented on June 27, 2005, stands rejected under 35 USC 102(b)as allegedly being anticipated by Laussac et al. (International Journal of Peptide Protein Research 26(4):425-428 1985).

The Examiner asserts that claim 1 is drawn to a peptide consisting of amino acid residues 2-25 of SEQ ID NO:1. The limitations "diagnostic for insulin resistance" and "biomarker" are inherent properties of the peptide, and do not impart any particular structural changes to the natural amino acid structure.

Laussac et al. disclose a peptide consisting of residues 1-24 of the human serum albumin peptide. This peptide is the same as residues 2-25 of SEQ ID NO:1. This peptide is used in mass spectra experiments, and thus, the Examiner determines that the peptide of Laussac et al. is the same composition as being claimed in instant claim 1.

Claim 1 has been cancelled, rendering the above-rejection under 35 USC 102(b) moot. Thus, Applicants respectfully request that this rejection now be withdrawn.

Claim 1, as presented on June 27, 2005, also stands rejected under 35 USC 102(b)as allegedly being anticipated by Roehr et al. (Liebigs Annalen der Chemie 9:881-884 1988).

The Examiner asserts that Roehr et al. disclose a peptide consisting of amino acid residues 1-24 of the human serum albumin peptide. This peptide is the same as residues 2-25 of SEQ ID NO:1. This peptide is used in mass spectra experiments, and thus, the Examiner determines that the peptide of Roehr et al. is the same composition as being claimed in instant claim 1.

Claim 1 has been cancelled, rendering the above-rejection under 35 USC 102(b) moot. Thus, Applicants respectfully request that this rejection now be withdrawn.

Rejections under 35 USC 112, second paragraph

Claims 1 and 36-43, as presented on June 27, 2005, stand rejected under 35 USC 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner asserts that in claim 1, the metes and bounds of "diagnostic for insulin resistance" in reference to a short peptide are unclear. This phrase appears to recite an inherent property of the peptide, and does not further limit the structure itself.

The Examiner asserts that in claim 36, the metes and bounds

of "in a manner effective to maximize elucidation of discernible fragments..." are unclear. This is not a positive active method step which clearly sets forth how this particular method step is to be carried out. Step c) in claim 36 is unnecessarily wordy.

The Examiner further asserts in claims 41-42, if the antibody is from a sample from a patient, how is it bound to a solid support? Similarly in claim 43, how does one label the antibody in the patient sample?

Claim 1 has been cancelled, thus rendering the part of the above rejection drawn to claim 1 moot.

Claim 36 has been amended to clearly delineate the steps of the claimed method(for diagnosing insulin resistance) and to clarify that the diagnosing of insulin resistance is accomplished by determining the presence of the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1. The biopolymer marker was found in patients having a history of insulin resistance (see the table in Figure 1).

Step (a) of claim 36 has been amended to clarify how the mass spectrometric analysis is carried out. Prior art mass spectrometric techniques often failed to identify the entire range of proteins present in a sample; for example, the proteins present in the greatest amounts were most easily identified by these techniques. The claimed method overcomes this limitation of the prior art by

the use of preparatory steps, such as chromatography and electrophoresis, prior to analysis of a sample using mass spectrometric techniques. These preparatory steps help to maximize the diversity of biopolymers discernible in a sample; i.e. the preparatory steps of the instant invention allow the identification of more biopolymers (including the less abundant proteins) present in a sample than previous methods allow. Thus, it is important for the claim to recite that a sample can be more throughly analyzed (maximized analysis) using the claimed method over prior art methods. See the abstract; page 11, lines 1-14; page 12, lines 2-6; page 17, lines 15-18 and page 20, line 7 to page 25, line 9 of the instant specification as originally filed.

Steps (a) and (b) of claim 36 have been amended to clarify how the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1 is identified in a sample. It is well known to the skilled artisan that mass spectral profiles are reproducible. Thus, the mass spectral profile of the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1, as shown in Figure 2, can be used as a reference against which to compare unknowns. For example, if the characteristic mass spectral profile of the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1 is matched to a mass spectral profile obtained in an analysis of an unknown sample, then the biopolymer marker is determined to be

present in the sample and is therefore indicative of insulin resistance in the patient from which the sample was obtained (Figure 2 and page 27, lines 17-23 of the instant specification as originally filed) .

Accordingly, Applicants respectfully submit that claim 36 clearly sets forth the steps by which the claimed method is carried out.

Claim 41 has been amended to clarify that the antibody of step (b) binds to the peptide of step (a). The specification as originally filed clearly contemplates kits useful for diagnosing insulin resistance that comprise the biopolymer marker consisting of amino acid residues 2-25 of SEQ ID NO:1 and an antibody which binds to this biopolymer marker; see for example, page 17, line 19 to page 18, line 7; pages 27, lines 17-23; page 28, lines 1-8 and page 31, line 8 to page 33, line 2.

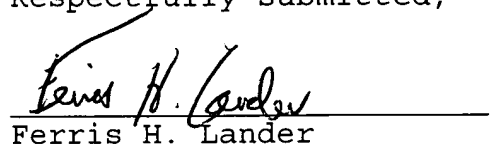
Thus, Applicants clearly claim a kit for diagnosing insulin resistance which contains a peptide (amino acid residues 2-25 of SEQ ID NO:1) and an antibody which binds to the peptide.

Accordingly, Applicants have now clarified the metes and bounds of the claims (36-43) and respectfully request that the above-discussed rejections under 35 USC 112, second paragraph, be withdrawn.

CONCLUSION

In light of the foregoing remarks and amendments to the claims, it is respectfully submitted that the Examiner will now find the claims of the application allowable. Favorable reconsideration of the application is courteously requested.

Respectfully submitted,



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